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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
BAEK, BONG-SOOK	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,918	BEHNAM, DARIUSH	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5 and 7-17* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-12 and 16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on April 8, 2009 is acknowledged. Claims 2, 4, and 6 have been canceled and claims 13-15 have been withdrawn. Claims 1, 3, 5, 7-12, and 16-17 are under examination in the instant office action.

Applicants' arguments, filed on April 8, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections. New grounds of rejection are necessitated by the following amendments: added limitations such as "emulsifiers as non-ionic polysorbates" in line 3 of claim 1 and "with the concentrate.....and polysorbate" in lines 5-7 of claim 1 and amendments in claims 16-17.

Claim objections

Claim 1 and 8 is objected because of the following informalities: typographical errors. The term "and or" in line 7 should be corrected to –and/or--. The number "4" in line 3 of claim 8 should be deleted.

Claims 16-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Since the close-ended language "consisting of", which excludes any additional element, is used in claim 1, additional component cannot be added, thus the scope of claims 16-17, which includes additional components, is broader than those of claim 1.

35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the exact percentages of 82.95%, 3.2%, 3.6%, and 10.25% may be supported by the disclosure (p3-4), there is no support for about 82.95%, about 3.2%, about 3.60% and about 10.25%. For instance, the interpretation of about 82.95 encompasses 80.01, 80.02....82.91, 82.95...85.93...., which are far different from about 85%. The same interpretation is applied to the other percentages. This raises a new matter issue. Thus, the term "about" should be deleted. In addition, the examples with a specific percentage of each ingredient in the specification use only one polysorbate (e.g., polysorbate 80). Thus, plural "polysorbates" should be corrected as "polysorbate" in claim 8.

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 7-12, and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

Claim 1 recites "water-free concentrate consisting of……", and then adds the following limitation, "with the concentrate comprising……..".

Using the closed-ended language "consisting of" with open-ended language "comprising" together renders the claim indefinite since it is unclear whether additional elements can be added or not, thus one of ordinary skill in the art would not ascertain the metes and bounds of the subject matter.

It is unclear whether "triglyceride" in line 6 refers to "medium-chained triglyceride or triglyceride mixture" in line 2 since it dose not utilize "the" or "said". Also, it is unclear whether "triglyceride" in line 6 and "polysorbate" in lines 6 and 7 are the same as or different from "triglyceride" in line 2 and "non-ionic polysorbate" in lines 3-4, respectively.

In addition, when the ratio of the polysorbate to the remaining ingredients in lines 8-9 is calculated, it is unclear which amount of the polysorbate should be used, the amount of the first

solubilizate, the second solubilizate, or total amount of both. Also, it is unclear what "the sum of the proportions by weight of the remaining ingredients" in line 9 means and what is included or excluded by "the remaining ingredients".

Finally, it is unclear what is meant by "non-ionic polysorbate" in line 3. Currently, there is no known ionic-polysorbate. It is unclear whether Applicants mean something else by that recitation. Otherwise, it is redundant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, 7-12, and 16-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent application publication 2003/0165438 (publication date: 9/4/2003)

in view of US patent application publication 2004/0081670 (publication date: 4/29/2004) and US patent 6,277,842 (issue date: 8/21/2001).

US 2003/0165438 teaches a essentially water-free composition containing ubiquinone Q_{10}, an emulsifier such as polysorbate 80, light oil containing medium chain triglyceride such as safflower oil (abstract; claims 2 and 4). US 2003/0165438 further teaches that the preferable content of ubiquinone Q_{10}, safflower oil and emulsifier such as polysorbate 80, light oil containing medium chain triglyceride are about 3%, about 8-20%, more preferably 12-15%, and about 50-85% by weight of the composition, respectively (claims 3, 5, and 8). Also, it discloses that the ratio by weight of the polysorbate to the sum of the proportions by weight of the remaining ingredients is about 5.5:1 (p9, example 1). In addition, it discloses the following production examples: production example 1 containing 30g of coenzyme Q_{10} (3% ubiquinone Q_{10}), 820g of the emulsifier polysorbate 80 (82%), and 150 g of safflower oil (15%) and production example 2: 50g of coenzyme Q_{10} (5% ubiquinone Q_{10}), 790g of the emulsifier polysorbate 80 (79%), and 160 g of safflower oil (16%) ([0039] and [0040]), which have the same ingredients as the first solubilizate recited in the instant claim 1. Finally, it teaches that the concentrate created according to the production examples can be processed in soft and/or hard gelification as a laminate and/or filling in various food items, such as chocolate, chewing gum etc. and in undiluted, but preferably in diluted form, the described concentrates can be packaged into drip bottles or drinking ampules (considered as non-alcoholic drink or similar food stuff).

It does not specifically teach the second solubilizate comprising α-lipoic acid and polysorbate and some of specific percentage of ubiquinone Q_{10}, a polysorbate, α-lipoic acid, and triglycerides. Also, it dose not teaches the ratio of the concentrate recited in claims 17 and 18.

US 2004/0081670 teaches water-soluble concentrates of an active substance such as ubiquinone Q_{10} or α-lipoic acid with emulsifier such as polysorbate and triglyceride such as linoleic acid and a method of making the concentrate (abstract, [0012], example 1, and example 8, claims 1, 17-18). It further discloses that a concentrate containing an active substance such as ubiquinone Q_{10} or α-lipoic acid is prepared by heating and stiring with solubilizer such as a polysorbate, preferably polysorbate 80 and additionally adding linoleic acid while heated and then cooling down (claim 1 and examples 1 and 8). In addition, it discloses a water-free concentrate containing 130 g α-lipoic acid (13 %) and 870 g polysorbate 80 (87 %) in the example 8 ([0046]), which has the same ingredients as the second solubilizate recited in the instant claim 1 . It further teaches that the active substance content is approximately 20% or less (claim 23).

US patent 6,277,842 teaches a method for promoting weight and fat loss, comprising coadministrating α-lipoic acid, ubiquinone Q_{10}, L-carnitine, chromium, creatine, niacin, pyruvate, riboflavin, and thiamine. Also, it discloses that lipoic acid and ubiquinone Q_{10} are potent antioxidants (column 3, lines 6-12 and line 36-39) and supplemental lipoic acid maintains a normal ratio of reduced –to-oxidized coenzyme Q_{10} (column 3, lines 28-29). In addition, the preferable effective amount of α-lipoic acid and coenzyme Q_{10} are between 30 mg and 6000 mg and between 10 mg and 2400 mg, respectively (column 3, lines 59-63).

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to combine the ubiquinone Q_{10} composition taught by US 2003/0165438 with the α-lipoic acid composition (concentrate) taught by US 2004/0081670 with a reasonable expectation of success because of the following reasons: US 2004/0081670 teaches α-lipoic acid concentrate is prepared in the similar way as ubiquinone Q_{10} concentrate. US patent 6,277,842 teaches that α-lipoic acid and ubiquinone Q_{10} are useful as a potent antioxidant and coexistence of α-lipoic acid and ubiquinone Q_{10} are beneficial for each other. Thus, one having ordinary skill in the art would have reasonably expected the combination of the compositions taught by US 2003/0165438 and US 2004/0081670 would provide an useful antioxidant composition and that the presence of α-lipoic acid would be beneficial for maintaining a normal ratio of reduced –to-oxidized coenzyme Q_{10}. *See KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395-96 (U.S. 2007), citing *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976) (stating "'when a patent simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious.").

Also, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize the specific percentage or ratio of ubiquinone Q_{10}, a polysorbate, α-lipoic acid, and triglycerides and the ratio of the concentrate in the drinks or food stuff based on the ranges taught by US 2003/0165438 and US 2004/0081670 and the effective amounts of α-lipoic acid and coenzyme Q_{10} taught by US patent 6,277,842. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or

temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). In the instant case, the claimed and disclosed ranges or percentage fall within the ranges of the prior art and the prior art suggests the percentage close to those claimed such that optimization is deemed well within the skill of the practitioner.

Response to Applicants' arguments:

First of all, applicants made arguments against the references individually, however one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With regard to US patent 6,277,842, the reference is cited for providing the motivation for combining α-lipoic acid concentrate and ubiquinone Q_{10} concentrate since it teaches both are useful as antioxidant and supplemental lipoic acid maintains a normal ratio of reduced –to-oxidized coenzyme Q_{10}.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Although 2003/0165438 and US 2004/0081670 teaches a concentrate comprising either α-lipoic acid or ubiquinone Q_{10}, 2003/0165438 and US 2004/0081670 teach that α-lipoic acid or ubiquinone Q_{10} can be made into water-free concentrate and US patent 6,277,842 teaches that both are useful as antioxidant and α-lipoic acid maintains a normal ratio of reduced –to-oxidized coenzyme Q_{10}, one having ordinary skill in the art would have been motivated to make the combination of the compositions taught by US 2003/0165438 and US 2004/0081670 on the expectation that the combination would provide a useful antioxidant composition and the presence of α-lipoic acid would be beneficial for maintaining a normal ratio of reduced–to-oxidized coenzyme Q_{10}. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine two compositions or treatment each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose…..The idea of combining them flow logically from their having been individually taught in the prior art." See *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Examiner's note

Applicants did not present any argument regarding the statutory double patenting rejection stated in the previous rejection mailed on 8/29/2008, thus the rejection can be properly maintained. However, it is noted that the claims of the instant invention and the copending application No.11/392957 have now been amended, thus the following nonstatutory double patenting rejection is made.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 7-12, and 16-17 are provisionally are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 7-13, and 18-20 of copending Application No. 11/392,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because both '957 application claims and the instant claims are drawn to a water-free concentrate consisting of the same ingredients (ubiquinone Q_{10}, α-lipoic acid, polysorbate, and medium-chained triglyceride (safflower oil) with the only difference in the ratio of the polysorbate to the sum of the remaining ingredients, that is, 4:1 to 5.5:1 (the instant claims) vs. 3.6:1 to 5.5: 1 (claims of'957 application). The claims of '957 application suggests the ratio close enough to those claimed such that optimization is deemed well within the skill of the practitioner.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
/Bbs/

BONG-SOOK BAEK
Examiner, Art Unit 1614